UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CARL JOHAN FRIDDLE and ERIN HILBUN

Appeal No. 2005-1792
Application No. 09/975,308

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3, all of the claims in the application. Claim 2 is representative and reads as follows:

2. An isolated expression vector comprising a nucleic acid sequence encoding the amino acid sequence of SEQ ID NO:9

The examiner relies on the following references:

Ji et al. (Ji), "G Proteins-coupled Receptors," The Journal of Biological Chemistry, Vol. 273, No. 28, pp. 17299-17302 (1998)

Bork, et al. (Bork), "Predicting functions from protein sequences – where are the bottlenecks?," Nature Genetics, Vol. 18, pp. 313-318 (1998)

Yan et al. (Yan), "Two-Amino Acid Molecular Switch in an Epithelial Morphogen That Regulates Binding to Two Distinct Receptors," Science, Vol. 290, pp. 523- 527 (2000)

Claims 1-3 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility.

We affirm.

Background

"[M]embrane receptor proteins are often involved in transduction pathways that control cell physiology, chemical communication, and gene expression. A particularly relevant class of membrane receptors are those typically characterized by the presence of 7 conserved transmembrane domains. . . . Such, '7TM receptors' include a superfamily of receptors known as G-protein coupled receptors (GPCRs)." Specification, pages 1-2. "The present invention relates to the discovery, identification, and characterization of nucleotides that encode novel GPCRs and the corresponding novel GPCR (NGPCR) amino acid sequences. The NGPCRs . . . are transmembrane proteins that span the cellular membrane and are involved in signal transduction after ligand binding." Page 2. One of the NGPCRs has the amino acid sequence shown in SEQ ID NO:9, which is encoded by the nucleotide sequence of SEQ ID NO:8.

The specification does not say what ligand(s) bind to the protein of SEQ ID NO:9, or what signal is putatively transduced by the protein, or what role the protein plays in any physiological process. Nonetheless, the specification discloses that the protein of SEQ ID NO:9 and nucleic acids encoding it have several uses. For example, the specification contemplates "methods of using the described NGPCR gene and/or NGPCR gene products for the identification of compounds that modulate, i.e., act as

agonists or antagonists of, NGPCR gene expression and[/]or NGPCR gene product activity. Such compounds can be used as therapeutic agents for the treatment of a wide variety of symptoms associated with biological disorders or imbalances." Pages 4-5.

The specification states that "the unique NGPCR sequences described in SEQ ID NOS:1-20 are useful of the identification of protein coding sequence and mapping unique genes to one or more particular chromosome. . . . The sequences of the present invention are also useful as additional DNA markers for restriction fragment length polymorphism (RFLP) analysis, and in forensic biology." Page 4.

The specification also states that "[t]he NGPCR proteins or peptides, NGPCR fusion proteins, NGPCR nucleotide sequences, host cell expression systems, antibodies, antagonists, agonists and genetically engineered cells and animals can be used for screening for drugs . . . effective in the treatment of the symptomatic or phenotypic manifestations of perturbing the normal function of one or more NGPCR in the body." Page 7.

Finally, the specification discloses that a polymorphic position was identified in SEQ ID NO:8: position 146 can be either G or A, resulting in either Ser or Asn at amino acid 49 of SEQ ID NO:9. Page 8.

Discussion

The examiner rejected all of the claims as lacking a disclosed utility sufficient to satisfy 35 U.S.C. § 101.[1] The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34

[1] The examiner also rejected all of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, but that rejection is merely as a corollary of the finding of lack of utility. See the Examiner's Answer, page 7. Therefore, our conclusion with respect to the § 101 issue also applies to the § 112 issue.

USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373. "Consequently, because Fisher

that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

In this case, the examiner found the specification's disclosure to be inadequate:

> The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.
>
> . . . [T]here is no disclosure of the ligand(s), biological functions, or any physiological significance of the putative GPCR; there is no disclosure of any evidence indicating that the putative GPCR is a truly functional GPCR and is involved in signal transduction pathway involving G-proteins . . .; there is no disclosure of any evidence indicating that the nucleic acid sequences of the present invention are expressed at altered levels or forms in any specific, diseased tissue, as compared with the healthy control tissue. Thus, the claimed invention lacks a specific and substantial utility.

Examiner's Answer, pages 3-4. See also page 7 ("In summary, all the asserted uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed nucleic acids.").

Appellants argue that the claimed nucleic acids encode a protein with a high degree of similarity to known GPCRs and that "as 60% of the pharmaceutical products

currently being market[ed] by the entire industry target G-protein coupled receptors (Gurrath, 2001, Curr. Med. Chem. 8:1605-1648 . . .), a preponderance of the evidence clearly weighs in favor of Appellants' assertion that the skilled artisan would readily recognize that the presently described sequences have a specific . . ., credible, and well-established utility." Appeal Brief, pages 9-10.

We do not agree that the characterization of the claimed nucleic acids as encoding G protein-coupled receptors is sufficient to establish their utility. The specification states that "membrane receptor proteins are often involved in transduction pathways that control cell physiology, chemical communication, and gene expression." Page 1. The specification provides no information regarding what biological functions or activities involve the polypeptide encoded by the instantly claimed nucleic acids, or what ligand binds to the protein of SEQ ID NO:9, or what signal (if any) is transduced by the protein in response to ligand binding.

Thus, the record does not support Appellants' position that the characterization of a polypeptide as a G protein-coupled receptor would have suggested a specific biological function, or any other basis for patentable utility, to a person skilled in the art at the time the application was filed. In the terms used by the Fisher court, such a characterization does not provide a substantial utility because it does not show that the claimed invention is useful as disclosed in its current form, only that it may be useful at some future date after further research: the specification does not disclose a significant and presently available benefit to the public. Cf. Fisher, 421 F.3d at 1371. Mere characterization as a GPCR also fails to provide a specific utility, because it does not "provide a well-defined and particular benefit to the public." Id.

Appellants also argue that the claimed nucleic acids "can be represented using a gene chip format to provide a high throughput analysis of the level of gene expression" (Appeal Brief, page 10); that they are useful in mapping human chromosomes (id., pages 11-12); and that they can be used to "specifically define that portion of the corresponding genomic locus that actually encodes exon sequence" (id., page 12).

We find that none of these uses meet the requirements of § 101. In this case, as in Fisher, the generic uses asserted by Appellants – assessing gene expression, mapping human chromosomes, and identifying exon sequences – are neither substantial nor specific. Like in Fisher, these uses are "merely hypothetical possibilities, objectives which the claimed [cDNAs], or any [cDNA] for that matter, could possibly achieve, but none for which they have been used in the real world." Fisher, 421 F.3d at 1373 (emphasis in original). Therefore, they are not substantial utilities.

Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome. Because nothing about Appellants' asserted utilities sets the claimed nucleic acids apart from any other human cDNA, Appellants have "only disclosed general uses for [the] claimed [cDNAs], not specific ones that satisfy § 101." Id. at 1374.

Finally, Appellants argue that the identified polymorphism in SEQ ID NO:8 makes the nucleic acids useful in "forensic analysis." Appeal Brief, pages 4-6.

We do not agree that the disclosed polymorphism establishes the utility of the claimed nucleic acids. First, Appellants' argument lacks support in the specification or in the evidence of record. The specification discloses the presence of a polymorphism in SEQ ID NO:8 (page 8) but discloses no utilities based on detection of the polymorphism.

In particular, the specification does not disclose that the polymorphism is a useful marker for forensic analysis.[2]

In addition, the polymorphism-based utility is neither substantial nor specific. It is not substantial because it is merely a hypothetical possibility, an objective which the disclosed polymorphism, or any polymorphism for that matter, could achieve, but not one for which the claimed nucleic acids have been used in the real world. See Fisher, 421 F.3d at 1373. It is not specific because nothing about the asserted utility sets apart the polymorphism in the claimed nucleic acids from any other polymorphism found in the human genome. See id. at 1374.

Summary

The specification does not disclose a specific and substantial utility for the claimed nucleic acids, as required by 35 U.S.C. § 101. We therefore affirm the examiner's rejection of claims 1-3.

[2] The specification (page 4, lines 29-31) states that "[t]he sequences of the present invention are also useful as additional markers for restriction fragment length polymorphism (RFLP) analysis, and in forensic biology." This passage, however, does not refer to the usefulness of the polymorphism in SEQ ID NO:8 but only generically to the use of "the sequences of the present invention . . . in forensic biology." Appellants have provided no evidence to show that the cited passage would have been understood by those skilled in the art to mean that the claimed sequences are useful because of the polymorphism found therein.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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